



UNITED STATES PATENT AND TRADEMARK OFFICE

[Signature]
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,295	11/06/2003	Joseph Barbosa	QA0253 NP	8067

23914 7590 08/30/2006

LOUIS J. WILLE
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/702,295

Applicant(s)

BARBOSA ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10,15,16 and 20-22 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4,6-10,15,16 and 20-22 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 6-10, 15, 16 and 20-22 are pending in the application.

This action is in response to applicants' amendment dated June 19, 2006.

Claims 1-4, 6-10, 15, 16, 20 and 21 have been amended, claims 5 and 17-19 have been canceled and claim 22 is newly added.

Response to Arguments

Applicant's arguments filed June 19, 2006 have been fully considered with the following effect:

1. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 2) of the last office action, which is hereby **withdrawn**.
2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 3) of the last office action, which is hereby **withdrawn**.
3. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 4a), b), c), d), e), f), g), h), j), k), l), m), n), o), p), q), r), s), t), u), v), w), x), af), ag), ah), ai), aj) and ak) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled i), y), z), aa), ab), ac), ad) and ae) the applicants' amendments and remarks have been fully considered but they are not found persuasive.

i) The applicant's stated that they have deleted the limitation "haloalkyl" from the definition of Y⁵ in claim 3. However, claim 3 has not been corrected with respect to "haloalkyl" in the definition of Y⁵.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention, for reasons of record.

y) The applicant's stated that Z is -NR³R⁴ where R³ can be H and R⁴ can be alkyl substituted by T⁴ (which can be ethyl substituted by "-T¹²N(R¹⁶)-T¹³-T¹⁰", or "-NHC(O)CH₃"). The applicants also pointed to the response to rejections labeled 4df), 4g), 4t) and 4w) where the moiety "-T¹²N(R¹⁶)-T¹⁵-T¹⁰" was amended to "-T¹²N(R¹⁶)-T¹³-T¹⁰" in the Specification and independent claims 1 and 6. However, the amendment to the definition of T¹-T⁹ in the Specification and in claims 1 and 6 presents new matter as set forth below and thus the lack of antecedent basis for the moiety -NH-CH₂CH₂NHC(O)CH₃ is herein maintained in view of the presence of the new matter which must be deleted in response to this office action.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention, for reasons of record.

z) The applicant's stated that Z is -NR³R⁴ where R³ and R⁴ are taken together to form a heterocyclo (pyrrolidinyl) which can be substituted by T⁴ which

Art Unit: 1624

can be " $-T^{12}N(R^{16})-T^{13}-T^{10}$ ", or " $-NHC(O)CH_3$ ". The applicants also pointed to the response to rejections labeled 4df), 4g), 4t) and 4w) where the moiety " $-T^{12}N(R^{16})-T^{15}-T^{10}$ " was amended to " $-T^{12}N(R^{16})-T^{13}-T^{10}$ " in the Specification and independent claims 1 and 6. However, the amendment to the definition of T^1-T^9 in the Specification and in claims 1 and 6 presents new matter as set forth below and thus the lack of antecedent basis for the moiety 3- $CH_3C(O)NH$ pyrroidin-1-yl is herein maintained in view of the presence of the new matter which must be deleted in response to this office action.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record.

aa) The applicant's stated that R^5 can be an (aryl)alkyl (i.e. benzyl) that can be substituted by T^7 which can be " $-T^{12}N(R^{16})-T^{13}-T^{10}$ ", or " $-NHSO_2(alkyl)$ ". The applicants also pointed to the response to rejections labeled 4df), 4g), 4t) and 4w) where the moiety " $-T^{12}N(R^{16})-T^{15}-T^{10}$ " was amended to " $-T^{12}N(R^{16})-T^{13}-T^{10}$ " in the Specification and independent claims 1 and 6. However, the amendment to the definition of T^1-T^9 in the Specification and in claims 1 and 6 presents new matter as set forth below and thus the lack of antecedent basis for the moiety $-4-CH_3CH_2SO_2NH$ benzyl is herein maintained in view of the presence of the new matter which must be deleted in response to this office action.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record.

ab) The applicant's stated that R^5 can be an (aryl)alkyl (i.e. benzyl) that can be substituted by T^7 which can be " $-T^{12}N(R^{16})-T^{13}-T^{10}$ ", or " $-NHSO_2(alkyl)$ ". The applicants also pointed to the response to rejections labeled 4df), 4g), 4t) and 4w) where the moiety " $-T^{12}N(R^{16})-T^{15}-T^{10}$ " was amended to " $-T^{12}N(R^{16})-T^{13}-T^{10}$ " in the Specification and independent claims 1 and 6. However, the amendment to the definition of T^1-T^9 in the Specification and in claims 1 and 6 presents new matter as set forth below and thus the lack of antecedent basis for the moiety $-4-CH_3SO_2NHC(=O)benzyl$ is herein maintained in view of the presence of the new matter which must be deleted in response to this office action.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record.

ac) The applicant's stated that R^5 can be an (aryl)alkyl (i.e. benzyl) that can be substituted by T^7 which can be " $-T^{12}N(R^{16})-T^{13}-T^{10}$ ", or " $-NHSO_2(alkyl)$ ". The applicants also pointed to the response to rejections labeled 4df), 4g), 4t) and 4w) where the moiety " $-T^{12}N(R^{16})-T^{15}-T^{10}$ " was amended to " $-T^{12}N(R^{16})-T^{13}-T^{10}$ " in the Specification and independent claims 1 and 6. However, the amendment to the definition of T^1-T^9 in the Specification and in claims 1 and 6 presents new

Art Unit: 1624

matter as set forth below and thus the lack of antecedent basis for the moiety —4-CH₃CH₂CH₂SO₂NHbenzyl is herein maintained in view of the presence of the new matter which must be deleted in response to this office action.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record.

ad) The applicant's stated that R⁵ can be an (aryl)alkyl (i.e. benzyl) that can be substituted by T⁷ which can be "-T¹²N(R¹⁶)-T¹³-T¹⁰", or "-NH₂SO₂(alkyl)". The applicants also pointed to the response to rejections labeled 4df), 4g), 4t) and 4w) where the moiety "-T¹²N(R¹⁶)-T¹⁵-T¹⁰" was amended to "-T¹²N(R¹⁶)-T¹³-T¹⁰" in the Specification and independent claims 1 and 6. However, the amendment to the definition of T¹-T⁹ in the Specification and in claims 1 and 6 presents new matter as set forth below and thus the lack of antecedent basis for the moiety —4-(CH₃)₂CHSO₂NHbenzyl is herein maintained in view of the presence of the new matter which must be deleted in response to this office action.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record.

ae) The applicant's stated that R⁵ can be an (aryl)alkyl (i.e. benzyl) that can be substituted by T⁷ which can be "-T¹²N(R¹⁶)-T¹³-T¹⁰", or "-NH₂SO₂(alkyl)". The applicants also pointed to the response to rejections labeled 4df), 4g), 4t) and

Art Unit: 1624

4w) where the moiety " $-T^{12}N(R^{16})-T^{15}-T^{10}$ " was amended to " $-T^{12}N(R^{16})-T^{13}-T^{10}$ " in the Specification and independent claims 1 and 6. However, the amendment to the definition of T^1-T^9 in the Specification and in claims 1 and 6 presents new matter as set forth below and thus the lack of antecedent basis for the moiety $-4-CH_3CH_2SO_2NHbenzyl$ is herein maintained in view of the presence of the new matter which must be deleted in response to this office action.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record.

4. The applicants amendments and arguments are sufficient to overcome the objection of claim 16 labeled paragraph 5) of the last office action, which is hereby **withdrawn**.

In view of the amendment dated June 19, 2006, the following new grounds of rejection apply:

Specification

5. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing

Art Unit: 1624

the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

6. The amendment filed June 19, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: $-T^{12}N(R^{16})-T^{13}-T^{10}$ in the definition of the substituents of the moieties in subparagraph (i) and the moieties of T^1-T^9 in subparagraph (ii).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4, 6-10, 15, 16, 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) The moieties T^{11} and $-NHS(O)_t(T^{11})$ in the definition of R^7 subparagraph (ii) is not defined in the specification with respect to the genus. (Claim 1)

Art Unit: 1624

- b) The moiety $-T^{12}-N(T^{16})-T^{13}-T^{10}$ in the definition of the substituents on the T^1-T^9 moieties in subparagraph (i) is not defined in the specification with respect to the genus. (Claim 1)
- c) The moiety $-T^{12}-N(T^{16})-T^{13}-T^{10}$ in the definition of T^1-T^9 in subparagraph (ii) is not defined in the specification with respect to the genus. (Claim 1)
- d) The moiety haloalkyl in the definition of T^{10} . (Claim 6 and claim 22)

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-4, 6-10, 15, 16 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the periods after the subparagraphs in the definition of R^{20} and R^{21} .

608.01(m) Form of Claims [R - 3]

>The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention.< While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. Each claim begins with a capital letter and ends with a period. **Periods may not be used elsewhere in the claims except for abbreviations.** See *Fressola v. Manbeck*, >36 USPQ2d 1211< (D.D.C. 1995). ** >Where a claim sets forth a plurality of elements or steps, each

Art Unit: 1624

element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).<

- b) Claim 6 and claim dependent thereon are vague and indefinite in that it is not known what is meant by the second occurrence of "T¹-T⁹ are each independently".
- c) Claim 8 is vague and indefinite in that it is not known what is meant by the second occurrence of the 4-NH₂-C(=O)-benzyl moiety as shown in the last line of page 14.
- d) Claim 16 is vague and indefinite in that it is not known what is meant by the periods after the subparagraphs.
- e) Claim 21 is vague and indefinite in that it is not known what is meant by the periods after the subparagraphs.
- f) Claim 22 is vague and indefinite in that it is not known what is meant by the second occurrence of the 4-NH₂-C(=O)-benzyl moiety as shown in the first line of page 21.
- g) Claim 22 is vague and indefinite in that it is not known what is meant by the variable "t", which is not defined within the claim.
- h) Claim 22 is vague and indefinite in that it is not known what is meant by the variable "T¹¹", which is not defined within the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

Art Unit: 1624

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Brenda L. Coleman
Primary Examiner Art Unit 1624
August 28, 2006